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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,544	10/16/2001	Avi J. Ashkenazi	GNE.2630P1C13	5195

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/978,544	**Applicant(s)** ASHKENAZI ET AL.	
	Examiner David J. Blanchard	**Art Unit** 1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 58-62.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

SHEELA HUFF
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claim 58 under 35 U.S.C. 102(b) as being anticipated by Struyk et al is maintained for reasons already of record. The reply filed 12/16/2005 argues that the art-recognized meaning of "specifically binds" is that the antibody specifically binds to a particular epitope of the PRO337 polypeptide of SEQ ID NO:523 without cross-reacting with other epitopes, including those found in the sequence disclosed in Struyk et al. Applicant reiterates that given the substantial divergence in sequence between the amino terminal regions of SEQ ID NO:523 and the polypeptide of Struyk et al, antibodies raised, for example, to the amino terminal region of SEQ ID NO:523 would specifically bind to SQE ID NO:523 and would not bind to the polypeptide of Struyk. This has been fully considered but is not found persuasive. Applicant presents "specific" binding in terms of an absolute. It binds only the antigen of interest and not any other antigen, i.e., that of Struyk. The assertion that the term "specifically binds" excludes cross-reactive antigens is not adequately defined or supported in the specification. Applicant is invited to point out where in the specification the term "specifically binds" is defined to exclude cross-reactive antigens consistent with applicant's arguments. Further, it is noted that the term "specifically binds" is not used in the immunological arts to connotate exclusive binding. That an antibody "cross-reacts", i.e., binds to more than one protein sequence, does not mean that the antibody does not "specifically bind" with both proteins. For example, antibodies may cross-react with two distinct antigens due to the presence of a homologous sequence in each protein, where the binding is considered to be "specific". Again, Applicant's arguments appear to be limiting the claims to particular epitopes of SEQ ID NO:523 not shared by the polypeptide of Struyk, however, the claims do not recite any particular epitope specificity (i.e., antibodies raised to the N-terminal region of SEQ ID NO:523) and the specification does not clearly define the term "specifically binds" such that one skilled in the immunological arts would recognize that the term is limited to antibodies that recognize unique epitopes of SEQ ID NO:523. Again, Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the rejection is maintained for reasons already of record and reiterated herein.

The rejection of claims 58-62 under 35 U.S.C. 103(a) as being unpatentable over Struyk et al in view of DeBoer is maintained for reasons already of record. The reply filed 12/16/2005 argues as above that Struyk et al does not disclose each and every claim limitation, i.e., antibodies that "specifically bind" to SEQ ID NO:523 and DeBoer does not cure this deficiency. This has been fully considered but is not found persuasive. The Examiners arguments above for Struyk et al apply here as well and in view of the art of DeBoer, one of ordinary skill in the art would have been motivated to modify the antibodies of Struyk et al such that the antibodies were monoclonal, humanized, antibody fragments and/or labeled antibodies because De Boer teach that humanized monoclonal antibodies are particularly useful in therapeutics since there is a lower chance of immune reaction when administered for human therapy, fragments are equivalent to full antibodies and labels are useful for visualization. Thus, there would be an advantage to producing these modified antibodies. Therefore, the rejection is maintained for reasons already of record and reiterated herein.

Respectfully,
David J. Blanchard
571-272-0827